

but solicits comment on whether and how specific events of various types should be considered to be "extreme."

With this document, the EPA is announcing the availability of revised draft guidance, along with examples of approved demonstrations on the EPA's Web site at <http://www.epa.gov/ttn/analysis/exevents.htm>. The EPA is providing the draft guidance to facilitate review of these materials by outside parties and to help ensure that the EPA's final guidance provides an efficient and effective process to make determinations regarding air quality data affected by events. The EPA notes that these draft guidance documents and the exceptional events Web site present examples to illustrate specific points. The example analyses and level of rigor are not necessarily required for all demonstrations.

After receiving timely submitted public comments on the draft guidance, the EPA plans to issue updated non-binding guidance. In addition, the EPA will continue to work closely with state, local, and tribal agencies to address issues arising during the development and submittal of exceptional event demonstration packages. The EPA is deferring a decision on whether to revise the Exceptional Events Rule.

The EPA invites public comment on all aspects of this draft guidance during the 60-day comment period. The draft guidance is not a regulation or any other kind of final action and does not establish binding requirements on the EPA or any state, local, or tribal agency or any emissions source. While the EPA has established a docket and is requesting public comment on the draft guidance, this procedure does not alter the nature or effect of the draft guidance and does not constitute a formal rulemaking process or require the EPA to respond to public comments in the updated guidance before the EPA or other agencies may use the guidance in reaching decisions making related exceptional event demonstration submittals. The EPA retains the discretion to revise its guidance, issue additional guidance, propose regulations as appropriate, and to use information submitted in public comments to inform future decisions. Because this draft guidance does not constitute a formal rulemaking action, the EPA is not required to respond to comments, but intends to consider significant comments in amending or updating the non-binding guidance. Following the 60-day comment period and review and incorporation of comments, the EPA expects to post the revised, final guidance documents at

<http://www.epa.gov/ttn/analysis/exevents.htm>.

Please refer to the **ADDRESSES** section above in this document for specific instructions on submitting comments.

### III. Internet Web Site for Guidance Information

Interested parties can find the draft guidance titled, Draft Guidance Documents on the Implementation of the Exceptional Events Rule, on the Exceptional Events Web site for this rulemaking at <http://www.epa.gov/ttn/analysis/exevents.htm>. The Web site includes examples of reviewed exceptional event submissions, best practices components, and links to publicly available support information and tools that the public may find useful.

Dated: June 26, 2012.

**Mary E. Henigin,**

*Acting Director, Office of Air Quality Planning and Standards.*

[FR Doc. 2012-16308 Filed 7-5-12; 8:45 am]

**BILLING CODE 6560-50-P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2012-0441; FRL-9352-9]

### Difenzoquat; Proposed Data Call-in Order for Pesticide Tolerance

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed order.

**SUMMARY:** This document proposes to require the submission of various data to support the continuation of the tolerances for the pesticide difenzoquat. Pesticide tolerances are established under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** Comments must be received on or before September 4, 2012.

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2012-0441; FRL-9352-9, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- **Mail:** OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), Mail Code: 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001.

- **Hand Delivery:** To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Eric Miederhoff, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (703) 347-8028; email address: [miederhoff.eric@epa.gov](mailto:miederhoff.eric@epa.gov).

### SUPPLEMENTARY INFORMATION:

#### I. General Information

##### A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to, those involved with:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

##### B. What should I consider as I prepare my comments for EPA?

1. **Submitting CBI.** Do not submit this information to EPA through [regulations.gov](http://www.regulations.gov) or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI

must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
- ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- iv. Describe any assumptions and provide any technical information and/or data that you used.
- v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- vi. Provide specific examples to illustrate your concerns and suggest alternatives.
- vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- viii. Make sure to submit your comments by the comment period deadline identified.

## II. FFDCA Data Call-In Authority

In this document, EPA proposes to issue an order requiring the submission of various data to support the continuation of the difenzoquat tolerances at 40 CFR 180.369. Under section 408(f) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(f), EPA is authorized to require, by order, submission of data “reasonably required to support the continuation of a tolerance” when such data cannot be obtained under the Data Call-In authority of section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136a(c)(2)(B), or section 4 of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2603. A section 408(f) Data Call-In order may only be issued following notice and a comment period of not less than 60 days.

After the 60-day comment period closes, the Agency will respond to comments, if appropriate, and may issue a final order requiring the submission of various data for difenzoquat in the **Federal Register**. A section 408(f) Data Call-In order must contain the following elements:

1. A requirement that one or more persons submit to EPA a notice

identifying the person(s) who commit to submit the data required in the order;

2. A description of the required data and the required reports connected to such data;

3. An explanation of why the required data could not be obtained under section 3(c)(2)(B) of FIFRA or section 4 of TSCA; and

4. The required submission date for the notice identifying one or more interested persons who commit to submit the required data and the required submission dates for all the data and reports required in the order. (21 U.S.C. 346a(f)(1)(C)).

If EPA issues such an order, persons who are interested in the continuation of the difenzoquat tolerances must notify the Agency by completing and submitting the required “§ 408(f) Order Response” form (available in the docket) within 90 days after publication in the **Federal Register**.

The “§ 408(f) Order Response Form” requires the identification of persons who will submit the required data and lists the following options available to support the required data:

- a. Develop new data,
- b. Submit an existing study—submit existing data not submitted previously to the Agency by anyone,
- c. Upgrade a study—submit or cite data to upgrade a study classified by EPA as partially acceptable and upgradable,
- d. Cite an existing study—cite an existing study that EPA classified as acceptable or an existing study that has been submitted but not reviewed by the Agency.

If EPA does issue a final order requiring the submission of data on difenzoquat and if the Agency does not receive a § 408(f) Order Response Form identifying a person who agrees to submit the required data within 90 days after publication of the final order, EPA will proceed to revoke the difenzoquat tolerances at 40 CFR 180.369. Such revocation order is subject to the objection and hearing procedure in FFDCA section 408(g)(2), but the only material issue in such a procedure is whether a submission required by the order was made in a timely fashion.

Additional events that may be the basis for modification or revocation of difenzoquat tolerances if a final order requiring data is issued include, but are not limited to, the following:

1. No person submits on the required schedule an acceptable proposal or final protocol when such is required to be submitted to the Agency for review.
2. No person submits on the required schedule an adequate progress report on a study as required by the order.

3. No person submits on the required schedule acceptable data as required by the final order.

4. No person submits supportable certifications as to the conditions of submitted data, where required by order and where no other cited or submitted study meets the data requirements the study was intended to fulfill.

## III. Regulatory Background for Difenzoquat

Difenzoquat is an herbicide. It is not currently registered under FIFRA. Difenzoquat’s last FIFRA registration was canceled in 2010. However, 25 FFDCA tolerances remain for residues of difenzoquat on the following commodities: barley, cattle, goat, hog, horse, poultry, sheep, and wheat (40 CFR 180.369). Since there are currently no domestic registrations for difenzoquat, these tolerances are referred to as “import tolerances.”

The Agency completed a Reregistration Eligibility Decision (RED) for difenzoquat in September 1994. The RED evaluated the potential human health and ecological risks associated with all registered uses of difenzoquat, and concluded that difenzoquat products, when labeled and used as specified in the RED, did not pose unreasonable risk or adverse effects to humans or the environment. Additionally, in connection with its obligation under the Food Quality Protection Act of 1996 (FQPA), the Agency evaluated whether all difenzoquat tolerances in existence at the time of the passage of FQPA met the revised safety standard that the FQPA adopted for FFDCA section 408. A Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment Progress and Risk Management Decision (TRED) for Difenzoquat was completed in April 2002. The TRED concluded that the risks of difenzoquat met the revised safety standard in FFDCA section 408.

In August 2011, in response to a registrant’s interest in supporting tolerances for import purposes, the Agency completed a screening-level evaluation for difenzoquat. As there are no domestic registrations for difenzoquat products, the evaluation was limited to the potential dietary risk from exposure to difenzoquat residues in imported food commodities. The evaluation concluded that additional data are needed to support a new dietary risk assessment on exposure from imported food commodities. The necessary data include: a neurotoxicity battery; residue data for wheat hay, wheat forage, and barley hay; and an immunotoxicity study. These data

requirements are discussed in detail in Unit IV.

#### IV. Proposed Data Requirements

##### A. Proposed Data and Reports

Pursuant to FFDCA section 408(f), EPA has determined that additional data are reasonably required to support the continuation of the import tolerances for difenzoquat, which are codified at 40 CFR 180.369. These data cannot be obtained under FIFRA section 3(c)(2)(B) because difenzoquat is not registered under FIFRA and the data call-in authority under that section only extends to registered pesticides. These data cannot be obtained under TSCA because pesticides are excluded from coverage under that statute. 15 U.S.C. 2602(2)(B)(ii).

Accordingly, EPA proposes to issue a final order requiring the submission of the following data:

1. *Neurotoxicity Screening Battery (870.6200)*. *Rationale*. EPA does not have a neurotoxicity screening battery (870.6200) for difenzoquat. This is a data requirement under 40 CFR part 158 as a part of the data requirements for registration of a pesticide (food and non-food uses) and establishment of FFDCA tolerances. 40 CFR 158.500. The Neurotoxicity Screening Battery (870.6200) is designed to evaluate the potential adverse effects on the nervous system from exposure to pesticide chemicals. The acute neurotoxicity study is required to detect possible

effects resulting from a single exposure. The subchronic neurotoxicity study is intended to detect possible effects resulting from repeated or long-term exposure.

2. *Immunotoxicity Study (870.7800)*. A final report and protocol are required. *Rationale*. EPA does not have a functional immunotoxicity study (870.7800) for difenzoquat. This is a data requirement under 40 CFR Part 158 as a part of the data requirements for registration of a pesticide (food and non-food uses) and for establishment of a tolerance. 40 CFR 158.500. A functional immunotoxicity study under the Immunotoxicity Test Guideline (870.7800) is designed to evaluate the potential of a repeated chemical exposure to produce adverse effects (i.e., suppression) on the immune system. Immunosuppression is a deficit in the ability of the immune system to respond to a challenge of bacterial or viral infections such as tuberculosis (TB), Severe Acquired Respiratory Syndrome (SARS), or neoplasia.

3. *Crop Field Trials (860.1500)*—(wheat hay, wheat forage, and barley hay) *Rationale*. EPA does not have crop field trials (860.1500) for difenzoquat for the commodities wheat hay, wheat forage, or barley hay. Field trials are required for each commodity/commodity group under 40 CFR part 158. These data are used to establish the legal maximum residue that may remain on food and to assess the risk posed by the pesticide residue.

EPA guidelines recommend that crop field trials be designed to take into account where the crop is grown and how much of the crop is grown. Field trials are generally needed for each type of formulation because the formulation can have a significant effect on the magnitude of the pesticide residue left on the crop. Residue trials also need to represent the maximum application rate on the label and have a geographic distribution representative of the commodity/commodity group so that EPA can evaluate what level of residues may be present from use of the pesticide. On June 1, 2000 (65 FR 35069) (FRL-6559-3), EPA published in the **Federal Register** a Notice which provided detailed guidance on applying current U.S. data requirements for the establishment or continuance of tolerances for pesticide residues in or on imported foods. A copy of that Notice is available in the docket of this proposed order. That Notice contains instructions for determining number and location of field trials.

EPA is requesting comment on these proposed data requirements.

##### B. Proposed Dates for Submission of Data/Reports

The table below lists the time proposed for both the completion and submission of each study. The proposed submission date is calculated from the date of publication in the **Federal Register** of the final order.

Guideline requirement No.	Study title	Timeframe for protocol submission	Timeframe for data submission (months)
870.6200 .....	Neurotoxicity Screening Battery .....	Not Required .....	24
870.7800 .....	Immunotoxicity Study .....	6 months .....	12
860.1500 .....	Crop Field Trials (wheat hay, wheat forage, and barley hay) .....	Not Required .....	24

#### V. Statutory and Executive Order Reviews

As required by statute, this document proposing to require submission of data in support of tolerances is in the form of a proposed order and not a rule. (21 U.S.C. 346a(f)(1)(C)). Under the Administrative Procedures Act, orders are expressly excluded from the definition of a rule. (5 U.S.C. 551(4)). Accordingly, the regulatory assessment requirements imposed on rulemaking do not, therefore, apply to this action.

This document proposes to require data from any party interested in supporting certain tolerances. Because this proposed order is not a significant regulatory action it is exempt from review by the Office of Management and

Budget (OMB) under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), and also not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This proposed order also does not require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994). This proposed order does contain

information collections that have been approved by OMB under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*

This document proposes to require data from any party interested in supporting certain tolerances and does not impose obligations on any person or entity including States or tribes; nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal

governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled Federalism (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this proposed final rule. In addition, this proposed order does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

#### List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, difenzoquat, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 22, 2012.

Michael Goodis,

Director, Pesticide Re-evaluation Division,  
Office of Pesticide Programs.

[FR Doc. 2012-16295 Filed 7-5-12; 8:45 am]

BILLING CODE 6560-50-P

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

#### 50 CFR Part 17

[FWS-R9-ES-2012-0013; 4500030115]

RIN 1018-AY38

#### Endangered and Threatened Wildlife and Plants; Listing the Hyacinth Macaw

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Proposed rule; 12-month finding.

**SUMMARY:** We, the U.S. Fish and Wildlife Service, propose to list as endangered the hyacinth macaw (*Anodorhynchus hyacinthinus*) under the Endangered Species Act of 1973, as amended (Act). We are taking this action in response to a petition to list this species as endangered or threatened under the Act. This document, which also serves as the completion of the

status review and as the 12-month finding on the petition, announces our finding that listing is warranted for the hyacinth macaw. If we finalize this rule as proposed, it would extend the Act's protections to this species. We seek information from the public on this proposed rule and status review for this species.

**DATES:** *Comments:* We will consider comments and information received or postmarked on or before September 4, 2012.

*Public hearing:* We must receive requests for a public hearing by August 20, 2012 addressed to the contact specified in **FOR FURTHER INFORMATION CONTACT**.

**ADDRESSES:** You may submit comments by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments on Docket No. FWS-R9-ES-2012-0013.

- *U.S. mail or hand-delivery:* Public Comments Processing, Attn: FWS-R9-ES-2012-0013, Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, MS 2042-PDM; Arlington, VA 22203.

We will not accept comments by email or fax. We will post all comments on <http://www.regulations.gov>. This generally means that we will post any personal information you provide us (see the Information Requested section below for more information).

#### FOR FURTHER INFORMATION CONTACT:

Janine Van Norman, Chief, Branch of Foreign Species, Endangered Species Program, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive, Room 420, Arlington, VA 22203; telephone 703-358-2171. If you use a telecommunications device for the deaf (TDD), call the Federal Information Relay Service (FIRS) at 800-877-8339.

#### SUPPLEMENTARY INFORMATION:

##### Executive Summary

We were petitioned to list the hyacinth macaw, and 13 other parrot species, under the Endangered Species Act of 1973 (Act). During our status review, we found threats operating in aggregation and contributing to the risk of extinction of the species. Therefore, in this 12-month finding, we announce that listing the hyacinth macaw is warranted and are publishing a proposed rule to list this species as endangered under the Act. We are undertaking this action pursuant to a settlement agreement, and publication of this 12-month finding and proposed rule will fulfill our obligations under that agreement.

This action is authorized by the Endangered Species Act of 1973, as amended. It affects Part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations. The Act and its implementing regulations set forth a series of general prohibitions and exceptions that apply to all endangered and threatened wildlife. These prohibitions make it illegal for any person subject to the jurisdiction of the United States to "take" (includes harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or to attempt any of these) within the United States or upon the high seas; import or export; deliver, receive, carry, transport, or ship in interstate or foreign commerce in the course of commercial activity; or sell or offer for sale in interstate or foreign commerce any endangered wildlife species. It also is illegal to possess, sell, deliver, carry, transport, or ship any such wildlife that has been taken in violation of the Act. Certain exceptions apply to agents of the Service and State conservation agencies.

Permits may be issued to carry out otherwise prohibited activities involving endangered and threatened wildlife species under certain circumstances. With regard to endangered wildlife, a permit may be issued for the following purposes: for scientific purposes, to enhance the propagation or survival of the species and for incidental take in connection with otherwise lawful activities.

This regulatory action is not economically significant.

#### Background

Section 4(b)(3)(B) of the Endangered Species Act (Act) (16 U.S.C. 1533(b)(3)(B)) requires that, for any petition to revise the Federal Lists of Endangered and Threatened Wildlife and Plants that contains substantial scientific or commercial information that listing the species may be warranted, we make a finding within 12 months of the date of receipt of the petition ("12-month finding"). In this finding, we determine whether the petitioned action is: (a) Not warranted, (b) warranted, or (c) warranted, but immediate proposal of a regulation implementing the petitioned action is precluded by other pending proposals to determine whether species are endangered or threatened, and expeditious progress is being made to add qualified species to or remove species from the Federal Lists of Endangered and Threatened Wildlife and Plants. Section 4(b)(3)(C) of the Act requires that we treat a petition for which the requested action is found to be warranted but precluded as though